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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,694	01/31/2002	David L. Narum	05213-0463	1014

45311 7590 02/11/2005

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,694	NARUM ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/15/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-12 in the reply filed on December 17, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 1-16 are pending in the instant application, of which claims 13-16 are withdrawn from further consideration as being drawn to a non-elected invention.

Specification

1. The amendment filed April 12, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicants amendment to the continuing data statement included the recitation "both of which are hereby expressly incorporated by reference in their entireties." However, the only time at which incorporation by reference may take place is at the time of filing, any attempt to do so after the filing date is considered new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

1. Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies which bind EBA-175, does not reasonably provide enablement for antibodies which inhibit P. falciparum invasion into a red blood cell in vivo. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to isolated antibodies, wherein the antibody inhibits P. falciparum invasion of a RBC in vivo.

Facts that should be considered in determining whether a specification is enabling, or if it would require an undue amount of experimentation to practice the invention include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The Federal Circuit has noted, however, that only those factors that are relevant based on the facts need to be addressed. See Enzo Biochem. Inc. v. Calgene, Inc. 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir 1999).

Ohas et al (Infection and Immunity Vol. 72. No. 2, pp 735-741, 2004) set forth that region II of the 175 kDa erythrocyte-binding antigen (EBA) is considered a prime target for an invasion-blocking vaccine. Ohas measured antibody levels against region II of the EBA-175 of

P. falciparum in an area of malaria holoendemicity in Western Kenya. Ohas et al concluded that although antibodies against EBA-175 region II may be effective in suppressing some of the wild parasite strains, EBA-175 is unlikely to be effective as a monovalent vaccine against malaria, perhaps due to allelic heterogeneity or presence of sialic acid-independent strains. (See abstract).

Turning towards the Wands analysis. The instant specification provides no working examples of inhibiting binding of an EBA-175 protein to a RBC. (Factor 3). Furthermore, the nature of the invention is highly unpredictable given that Ohas et al has set forth that antibodies to EBA-175 region II are ineffective in inhibiting malaria, perhaps due to allelic heterogeneity or presence of sialic acid-independent strains. (Factors 1, 2, 4, 5, 7 and 8).

Given the lack of working examples, lack of guidance, and unpredictable nature of the invention, one of skill in the art would be forced into excessive experimentation to practice the instantly claimed invention.

3. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "cysteine rich region." One of skill in the art would be unable to determine the metes and bounds of the claim limitation. For instance, what percent level of cysteines are needed to be considered rich (e.g., 6%, 10%, 20%, etc)? Furthermore, at what level is the region merely cysteine average (e.g., 15%, 10%, 5%, 3%, etc)? Without a clear definition as to the metes and

bounds of the term "cysteine rich" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Sim et al.

The claims are directed to an isolated antibody, wherein the antibody binds a 5' cysteine rich region of an EBA-175 protein from a Plasmodium species.

Sim et al (WO 96/40766) disclose of isolated polypeptides useful in the treatment of malaria caused by P. falciparum or P. vivax, in particular the polypeptides are from the binding domains of the proteins in the DBL family, as well as SABP and DABP. Sim et al further define "DABP and SABP binding domains" as "a sequence from the cysteine rich, amino terminal region of DABP or SABP. (See Abstract and page 2). It is noted that Applicants specification refers to EBA-175 as having the same sequence described in Sim et al, (1990). (Specification page 6, lines 21-23). Sim et al further disclose of antibodies against these polypeptides as well as hybridomas which secrete the monoclonal antibody. (See pages 7-8).

It is further noted that Sim et al disclose the amino acid sequence of the instantly claimed SEQ ID NO: 1. (See Figure 1; SABP F2). While Sim et al do not teach of the "consisting of" fragment identified in SEQ ID NO: 1, (claim 5) the claim is drawn to "consisting of approximately..." Accordingly, the disclosure of Sim et al to fragments slightly larger than the recited SEQ ID NO: 1 is deemed to anticipate the claim language. Amendment of the claim to recite "consisting of SEQ ID NO: 1" would be sufficient to overcome this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
January 25, 2005